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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/774,188	03/20/2001	Gunther Sawatzki	REF/SAWATZKI	3636

7590 12/16/2003

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EXAMINER
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EVANS, CHARESSE L

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 12/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/774,188

Applicant(s)

SAWATZKI ET AL.

Examiner

Charesse L. Evans

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 14-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Action Summary*

Acknowledgement is made of the receipt of applicant's Petition for Extension of Time, Information Disclosure Statement and Request for Continued Examination, filed October 31, 2003.

The amendment filed on September 3, 2003, pursuant to 37 CFR 1.114, is considered the required submission, in which claims 1-13 were indicated as cancelled.

Claims 14-32 are active in this action.

### *Priority*

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d).

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15, 16, 22-26, 31 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim

the subject matter which applicant regards as the invention. The phrase "and/or" render the claims indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 14-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Green et al (US 5,792,754) in view of Paul (US 5,531,988). The claims are directed to

a composition comprised of a mixture of carbohydrates, characterized in that the mixture consists of two different carbohydrate components. Component A consists of at least one monosaccharide or at least one oligosaccharide of up to six monosaccharide units, or a mixture of two or more of these saccharides; component B consists of one polysaccharide or a mixture of two or more polysaccharides containing at least seven monosaccharide up to a maximum of 100 monosaccharide units and wherein the carbohydrate mixture component A is present in the amount from 5 to 95 weight percent and component B is present in the amount from 5 to 95 weight percent.

Green discloses a nutritional composition composed of oligosaccharides such as galacto-oligosaccharides and fructo-oligosaccharides, present in the amount of 8-70%. (column 2, line 4). Oligosaccharides are understood to comprise any saccharide containing at least two and up to 20 monosaccharide units. Especially preferred are oligosaccharides having an average chain length of between 3 and 9 monosaccharide units (column 3, lines 1-16). Regarding component B, the disclosed composition further contains soluble non-starch polysaccharides that include components such as inulin, beta-glucans, pectin, xanthan, carageenans and alginates (column 2, lines 2 and 47-59). This component is present in the amount of 15-50 weight percent. Examples of insoluble non-starch polysaccharides include cellulose and hemicellulose, present in the range of 15 to 45 weight percent (column 2, lines 3 and 60-67).

While the reference does not expressly teach applicant's claimed amounts of carbohydrate components A and B, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

The nutritional composition disclosed by Green will further contain digestible carbohydrates that may include monosaccharides, disaccharides and digestible oligo- and polysaccharides (column 4, lines 24-30). It has been shown that administration of fructo-oligosaccharides (FOS) enhances growth of the bifidobacteria population in the intestine, suppresses production of putrefactive factors, improves blood lipid levels in hyperlipidemia patients and provides relief from constipation (Paul '134, column 7, lines 16-24). Regarding the limitation requiring that the composition containing the carbohydrate mixture promote the growth of lactic acid bacteria in the large intestine of a human, the presence of the components within the disclosed carbohydrate mixture is all that is need to render obvious applicant's claims. When a component is included in a composition, all of its properties and advantages are inherent to the composition. Paul is cited to support this position.

The disclosed carbohydrate mixture does not contain glucose units linked at the alpha 1-4 or alpha 1-6 position.

The difference between the claimed invention and the cited prior art is that the cited art does not recite the exact concentrations as claimed by applicant. One of ordinary skill in the art, however, would have been motivated to manipulate the various concentrations of the carbohydrate components with the expectation of formulating a composition that is most effective in maintaining gut function and clearance of toxic compounds, by providing stool bulk and substrate to intestinal flora.

### *Conclusion*

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charesse L. Evans whose telephone number is 703-308-6400. The examiner can normally be reached on Monday -Thursday 7:00a - 4:30p; Alternating Fridays 7:00a - 3:30p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-

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308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Charesse L. Evans  
Examiner  
Art Unit: 1615

December 11, 2003

**THURMAN K. PAGE**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**